



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0524]

Listing of Ingredients in Tobacco Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised final guidance for industry entitled “Listing of Ingredients in Tobacco Products.” The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third

party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0524 for "Listing of Ingredients in Tobacco Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a

written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the revised draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New

Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Collins or Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised guidance for industry entitled "Listing of Ingredients in Tobacco Products." The revised guidance document is intended to assist persons making tobacco product ingredient submissions to FDA as required by the Tobacco Control Act.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given the requirement that ingredient listing submissions be submitted by May 8, 2018 (§ 10.115(g)(2)). We made this determination because FDA needs to timely communicate that the guidance presents a less burdensome policy that is consistent with the public health and clarifies ways in which tobacco product manufacturers and importers can submit ingredient listing submissions as required by section 904(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387d(a)(1)). Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

The Tobacco Control Act, enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health (Pub. L. 111-31, 123 Stat. 1776). Among its many provisions, the Tobacco Control Act added section 904 to the FD&C Act, establishing requirements for tobacco product ingredient submissions.

II. Significance of Guidance

This revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on listing of ingredients in tobacco products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This revised guidance refers to previously approved collections of information found in FDA regulations. The revised draft guidance includes information and recommendations for how to provide ingredient listing submissions for tobacco products. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in section 904(a)(1) of the FD&C Act have been approved under OMB control number 0910-0650.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised guidance at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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